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Radiological Follow-up of Transluminally Inserted Vascular Endoprostheses: An Experimental Study Using Expanding Spirals[1]

A technique for transluminal implantation of vascular endoprostheses was developed. Using a suitable instrument, 160 spiral-shaped prostheses of various forms and sizes were torsion-reduced in diameter and transluminally inserted under fluor scopy in our study population consisting of 65 dogs and five calves. At the target, the spirals were enlarged and re l ased from the carrier, whereupon they attached themselves to the vessel wall by elastic expansion. We implanted spirals into the vena cava or the thoracic and abdominal aorta, using the infrarenal aorta and the jugular or femoral vein for access. Angiography (the maximum follow-up was tw years) demonstrated that the operation was reproducable and that it could be planned. Angiography also demonstrated that the position of the spiral prosthesis was stable and that the spiral did not lead to stenosis, thrombosis, or perforation, providing an adequate technique was used. The side branches of the main vessels remained patent, even with several spiral coils across their orifices. The method can be clinically implemented and lends itself to many applications in the vascular field.

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To date vascular endoprostheses have only been implanted transluminally in the form of caval filters (1, 2), which limited their usage for embolization purposes. Transluminally implanted vascular prostheses that were expandable and self-adjustable at the requir d location could open up new potentials to vascular surgery. This kind of technique takes on additional value if the prostheses involved could be implanted not only from a larger to a smaller vessel but also from one that was peripheral to one that was central. We previously described the principles and first results of a technique that meets these requirements (3); however, this technique has since been improved and long-term experimental *in vivo* results extending over two years are now available.

MATERIALS AND METHODS

For our clinical application we developed an experimental prosthesis model, using variously shaped spiral springs (Medinvent SA, Lausanne, Switzerland) that were constructed of wires or bands of a non-corrosive inert spring steel (Fig. 1). The material used was a heat-treated steel alloy that is specially produced for medical purposes (Mediloy, Matthes AG, Basel, Switzerland).

The application of torque to the ends of these spiral springs, in the direction of the coils, increased the number of coils as it reduced the diameter of the spiral. This process was also reversible as long as the elasticity of the material was not exceeded. The relationship between the slack diameter at rest and the minimum diameter, *i.e.*, the maximum expansion factor, depended on the elasticity module, the strength and shape of the cross section of the material, as well as on the diameter at rest. Depending on the type of spiral spring, the purpose of the application and the location of the spring, this maximum expansion factor was between 1.2:1 and 5:1.

We developed *double helix* spirals, which had some very favorable mechanical properties (*e.g.*, a slightly tilting movement during the application of torque), wherever large diameters and high expansion factors were needed. The pressure exerted by the expanding spirals on the vascular wall could be planned in advance or calculated in retrospect (3). The insertion was carried out by means of a flexible instrument that tightened, expanded and released the spirals.

The animal experiments were carried out on 65 dogs and five calves, which were placed under general anesthetic. One hundred and sixty spiral springs of different shapes and sizes were implanted intra-aortally (n = 102) or intracavally (n = 58). Implantation into the venous system was accomplished from the periphery *via* the jugular or femoral vein (Fig. 2), while insertion into the thoracic aorta was accomplished *via* an infrarenal aortotomy. Implantation from the periphery proved impossible in dogs because of the small size of their femoral or carotid arteries. A standard 7-mm instrument was used to implant spirals measuring up to 35 mm in diameter (Fig. 3).

For the implantation, a vessel was selected and dissected. After placing a clamp distally and a snare centrally, we introduced the instrument through a small incision, using the snare for sealing. The spiral was enlarged by retorsion and released at the target site under fluoroscopic control. When this

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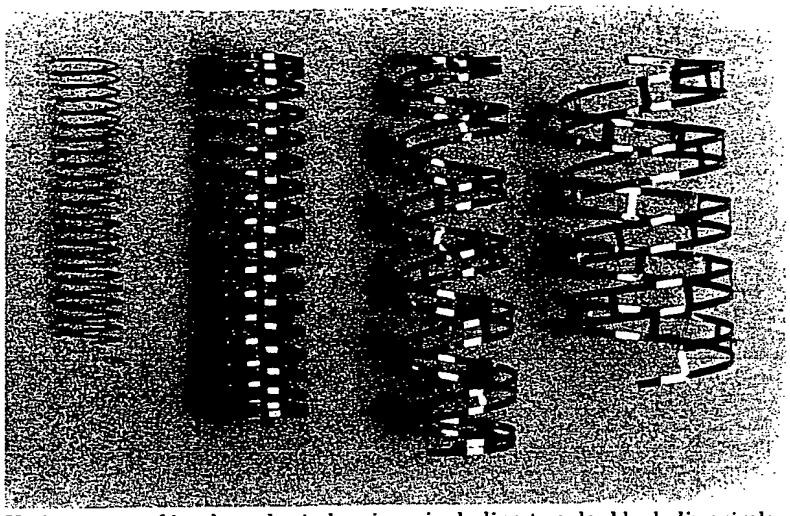
ms

Figure 1



Various types of implanted spiral springs, including two double-helix spirals.

was accomplished, the applicator was removed.

No drugs were administered during the entire postoperative period. The follow-up extended over a period of 24 months, with angiographic checks performed intraoperatively or in the immediate postoperative period, after two and six weeks, and at three, six, 12, and 24 month intervals.

RESULTS

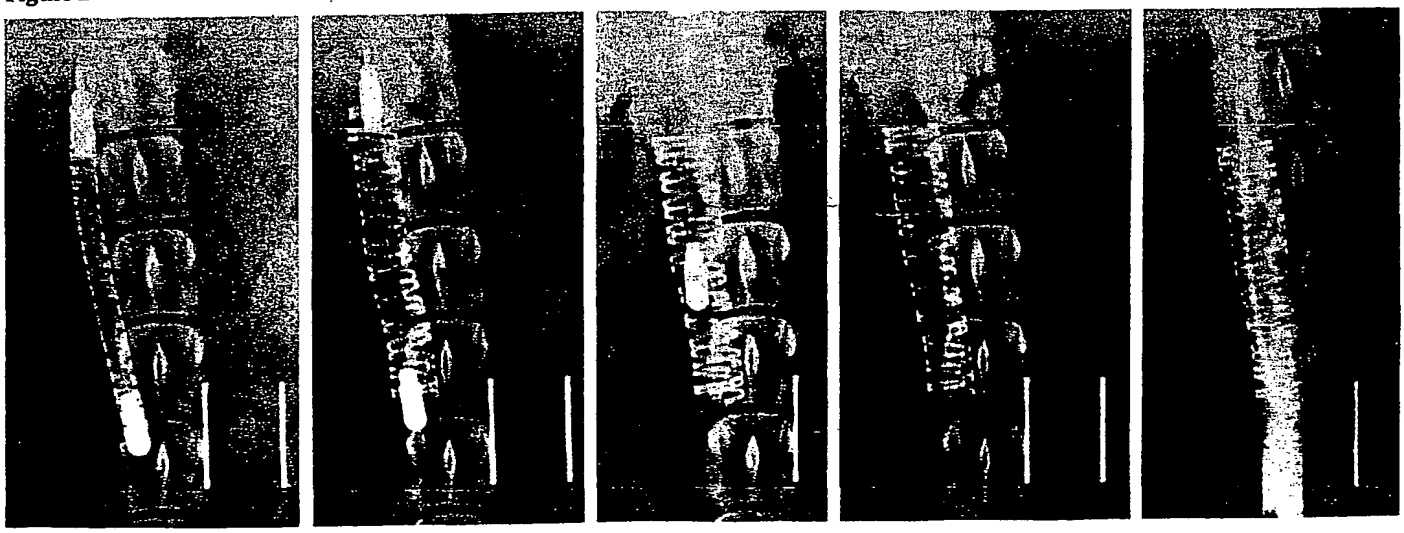
Using the technique we have described, spiral prostheses can be transluminally maneuvered to the target site under fluoroscopic control in an exact and reproducable manner. The *double helix* spirals adapt themselves to the varying diameters of a vessel, and the radiological checks along with the macroscopic and microscopic findings show their position to be stable (Figs. 4a and b) without threat of dislocation.

No perforations were observed even when the expansion pressure was 1000-mm Hg in the aorta and 300-mm Hg in the cava. The two exceptions noted were attributable to a technical mistake and to an infection in the aorta. The improved devices and techniques also eliminated vascular occlusions in the aorta (Fig. 5) or in the vena cava. In a few sporadic cases, some thrombi attached themselves to the wall and developed in the infrarenal vena cava within the first two weeks, but these showed no further tendency to progress. Side branches of the aorta (Fig. 6) or the vena cava (Fig. 7) remained patent even when crossed by several spiral coils.

DISCUSSION

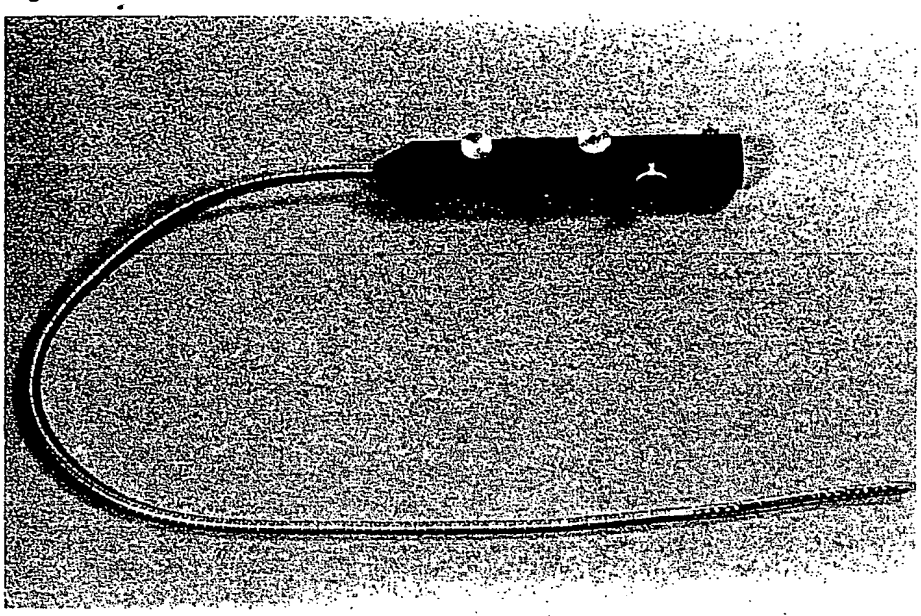
In 1969 Dotter attempted a percutaneous transluminal implantation of spiral springs into peripheral vessels (4). The animal experiments performed at this time were unsatisfactory because of the resulting stenoses. Secondary dislocations were also the rule. Later, Simon (5, 6) reported on his attempts to develop a novel cava filter which could be implanted percutaneously using the memory-alloy technique. When Schetky, in 1979, (7) described the main features of this technique and its possible medical applications Dotter (8) and Cragg (9) went back to their original idea. They recently reported on their progress, presenting the first results of their animal tests. Their methodology was to percutaneously insert a metal wire with a memory in taut. When heated to body temperature at the target place, this wire assumed a previously specified shape. While the technique seems fascinating and attractive, its implementation appears to be technically and biologically difficult. The uncertain biocompatibility of the nickel/titanium alloy (Nitinol) presents a problem as does the need to

Figure 2



Different stages of the transvenous implantation of a double-helix into the inferior vena cava (IVC) via the jugular vein. The slight bulge in the middle of the spiral indicates how the spring exactly adapts to fluctuations in size. The diameter of the spiral was 25 mm. The distance between the white markings is 20 mm.

Figure 3

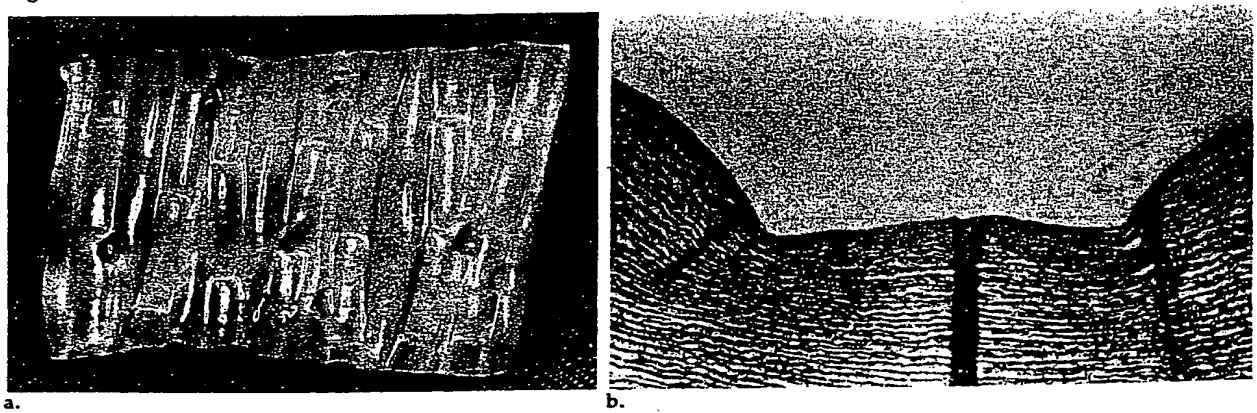


Device used for the transluminal implantation of double-helix spirals. The 10-cm long spiral was tightly wound at the end of the introducer. The instrument is highly flexible and features a central angiographic channel with an incorporated stop-cock. Controls, located in the handle, enlarge the spiral at its target by retorsion prior to its release.

Figure 5

Angiogram, 12 months after implantation of a double-helix spiral into the thoracic aorta of a dog. Because the spiral coils were covered by a thin, endothelisized neointimal layer, they appear to be outside the lumen. No stenosis developed, and the intercostal arteries were patent.

Figure 4

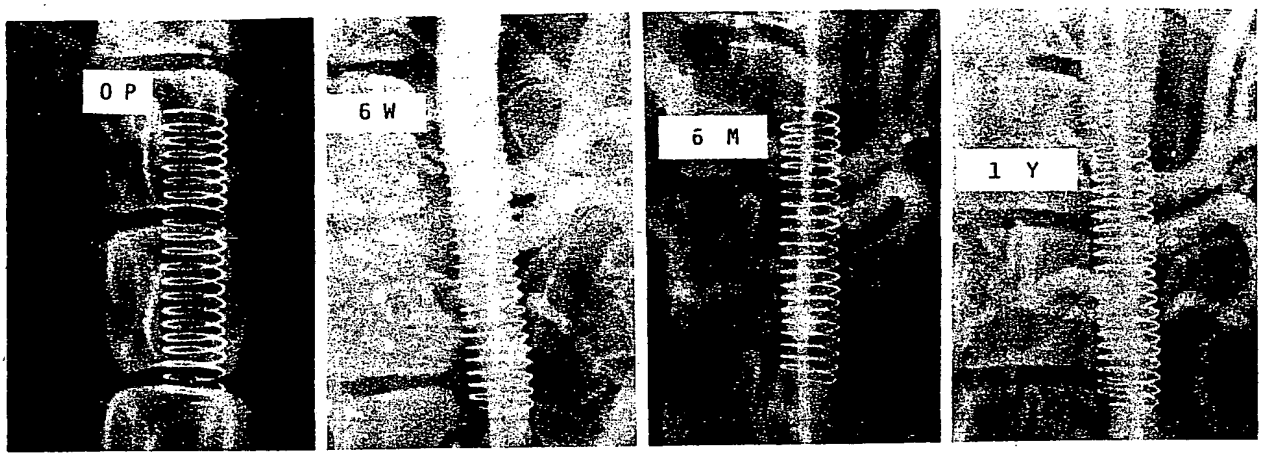


a.

b.

a. Aorta specimen six days after implantation of a double-helix. Only the negative cast remains, since the cut spiral coils had not yet been overgrown. The sharp contours of the H-shape prove that there was no movement. There are also no signs of thrombotic deposits or of vascular lesions. The intercostal arteries are patent.

b. Longitudinal section through the aorta wall, transverse to the spiral coil. The compression of the elastic lamellae from the expansion pressure of the spiral can be seen clearly. Proliferating intima have begun to grow over the metal band from both sides and were visible microscopically (van Gieson-Elastin × 100), proving that the position of the prosthesis was absolutely stable.



Multiple spiral coils cross the celiac trunk, the superior mesenteric artery, and the right renal artery. Angiographic checks after six weeks, six months, and one year showed that the aorta and the other side branches were patent without major stenoses.

prevent heat distortion of the metal during the implantation process. Dotter used pre-shaped small spirals from an alloy having a higher transition temperature, and he injected heated saline solution through the catheter to enlarge the spiral *in situ*.

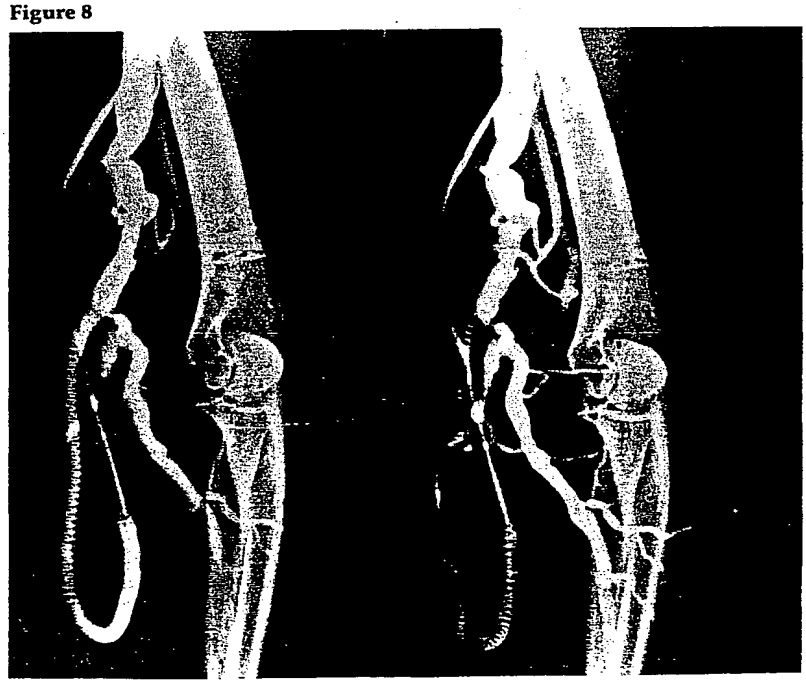
The torque method we developed is based on a comparatively simple mechanical principle, *i.e.*, the elastic malleability of high-grade spring steel. Since the elastic properties of a spiral spring are known, it is possible to achieve effects which are predictable and reproducable. The animal test results were proved angiographically, as well as macroscopically and microscopically; implantation in a specific spot was feasible and a stable position was guaranteed.

The stability of a vascular endoprosthesis is an absolute prerequisite for clinical use, but that stability depends on the type of *self-fixation* employed, since the prosthesis cannot be held in place by sutures. Fixation aids, like the hooks or spikes in caval filters, are unsuitable for long intravenous prostheses and are definitely dangerous in the arterial high-pressure system

Figure 7

Spiral spring in the IVC. The run-off of contrast medium was briefly interrupted by a balloon catheter, which allowed good retrograde filling of the hepatic veins. Both the vena cava and the entries to the hepatic veins were patent after 12 months.

Figure 8



Control angiogram six weeks after implantation of a spiral-supported bovine xenograft (Solcograft-P) as an arteriovenous shunt for chronic hemodialysis. The spiral spring prevented the graft from kinking and allowed bending of the elbow joint along with a continuous strong hemostatic compression, all without affecting the flow.

where they can cause vessel lesions. However, the fixation method that exerts pressure on the inner vascular wall as a result of an elastic expansion has turned out to be surprisingly favorable and safe. Questions regarding the calculability of the expansion pressure, the amount of pressure required for secure fixation, and the short and long-term reactions of the vascular wall have been answered thanks to theoretical considerations and animal experiments (3, 10).

Spiral prostheses can be produced as needed according to their intended application, the size of the vessel where they will be implanted and the amount or range of pressure required. Spirals do not have to duplicate the dimensions of a given vessel size down to the last millimeter; instead, they elastically adapt to the vessel's diameter within a certain range. Thus, for example, *double helix* spirals with a diameter of 32 mm can be implanted in vessels with diameters of 12 to 28 mm, without any affect on the stability of their position and without exceeding the acceptable pressure that the vessel wall can tolerate.

In theory, the only disadvantage to the torque method is the limitation imposed by the percutaneous implantation technique. Thus, if the diameter of the access applicator is limited to 3–4 mm the maximum diameter of the implanted spiral springs can only be 12–15 mm. The width of the metal band, however, can be varied within a wider range (10 mm and more), and combinations with microporous synthetics are also possible.

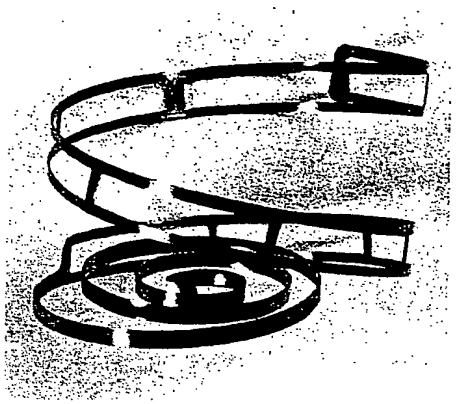
A sealing prosthesis, though conceivable and technically possible for internal bypasses (through the tight rolling of the spiral coils), is biologically not feasible. We cannot share Cragg's (9) optimism, because our own experience with tightly coiled spirals showed that a non-porous material substituting for a blood vessel leads to high-grade stenosis and finally to vascular occlusion.

The potential applications of the method are largely speculative at the present stage of development. Spiral prostheses can work as stents where the vessels or vascular substitute materials are exposed to compression, *e.g.*, where there are fibrous or tumorous processes or postoperative edemata or hematomata. They could also work in the compressed genuine lumen of an aneurysma dissecans. Another therapeutic aim is to prevent kinking in the joint region or to provide extra-anatomical vascular bypasses (spiral spring tube effect).

These were the objectives of a recently-started study involving a spiral-supported bovine xenograft as an arteriovenous shunt for chronic hemodialysis (11). This combination prevented kinking of the graft, allowed lasting compression for hemostasis after punctures, and did not affect the flow (Fig. 8). Other possible vascular applications are intimal dissections to stabilize and reinforce the vascular wall for the prevention of aneurysm in high-risk patients (Marfan syndrome). Prevention of recurrent stenosis after percutaneous transluminal angioplasty may also be considered. We previously developed and tested a spiral-shaped caval filter (12) and implanted it following the techniques described here. It attached itself to the vascular wall without causing lesions (Fig. 9).

This list describing the possible applications for spiral prostheses does not claim to be complete. Extravascular applications, as in the tracheo-bronchial system or the esophagus, should also be considered. There can be no doubt that the transluminal implantation of expanding, self-adjusting endoprostheses will take on increasing importance.

Figure 9



Prototype of a spiral caval filter (helix-filter) that can be transluminally implanted, whereupon it will fix itself to the caval wall by elastic force. The horizontal coils are responsible for the filtering function. The design allows transvenous extraction of the filter in the first two weeks after implantation.

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